REMARKS

The present application is directed to a method of treating a human or animal suffering from the effects of infection with *Yersinia pestis*, comprising administering to the human or animal, a therapeutically effective amount of a medicament comprising an antibody specific for *Yersinia pestis* F1-antigen, or a binding fragment thereof, and an antibody specific for *Yersinia pestis* V-antigen, or a binding fragment thereof. Claims 17-32 are pending, and Claims 1-16 are cancelled. Claims 25-32 are withdrawn for being directed to a non-elected invention. Claims 24 and 32 are amended. Applicants respectfully submit that no new matter is added and support for the amendments is found throughout the specification and claims as originally filed.

Specification

In the Office Action mailed April 9, 2007, the Examiner objected to the specification for failing to incorporate essential matter. Specifically, the Examiner stated that the sequence of the V-antigen is essential matter. Applicants respectfully submit that the specification is amended herein to recite the sequence of the V-antigen. Applicants respectfully submit that the instant application refers to WO 96/28551 for recitation of the V-antigen sequence. Applicants submit that WO 96/28551 issued as **U.S. Patent 5,985,285** on November 16, 1999. Accordingly, applicants have amended the instant application to incorporate the above U.S. Patent. To facilitate examination, Applicants wish to highlight that the **V-antigen sequence** as recited in WO 96/28551 corresponds to **SEQ ID NO: 2** of US Patent 5,985,285.

Applicants have amended the specification to identify the previously incorporated V-antigen sequence in a corresponding U.S. Patent. Applicants respectfully submit the above amendments overcome the objection and kindly request withdrawal of the objection.

Claim Objections

In the Non-Final Office Action mailed April 9, 2007, the Examiner objected to Claims 17-21 and 23-24, as being directed to non-elected subject matter. Applicants respectfully submit that the amendments to the claims overcome the rejection.

A Restriction Requirement was mailed February 8, 2007, requesting the election of one of five inventions. Applicants elected Group III, directed to **Claims 17-24**, drawn to methods of treating a *Yersinia pestis* infection comprising administering antibodies specific for *Yersinia pestis* V antigen and antibodies specific for *Yersinia pestis* F1 antigen. Claim 17 has been amended to delete the subject matter of Groups I and II.

In view of the foregoing, applicants respectfully request withdrawal of the claim objection.

Claim rejections under 35 U.S.C. §112, first paragraph

In the Non-Final Office Action mailed April 9, 2007, the Examiner rejected Claims 17-24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

Contrary to the Examiner's assertions on page 3 of the Office Action, the antigens of the instant application (V-antigen and F1 antigen of *Yersinia pestis*) were fully characterized and available to the public domain at the date of the present invention. As discussed above, with reference to WO 96/28551 and its equivalent, U.S. Patent (5,985,285), these patents are themselves the basis of a vaccine. Clearly, the existence of a U.S. Patent that relies on the availability of antigens to form the basis of a vaccine is an indicator that the U.S.P.T.O. has already established that the above antigens are fully characterized. It follows then that antibodies to the above F1 and V-antigens also meet the written description requirement, because one of ordinary skill in the art need only to have a complete knowledge of the antigen in order to be able to generate antibodies using entirely conventional and routine methods.

Applicants respectfully assert that the present application is distinguished from the Noelle case which failed, according to the Examiner, on the basis that the antigen was not properly characterized.

The Examiner has already stated that two monoclonal antibodies, Mab 7.3 and Mab F1-04-A-G1, meet the written description requirement. Applicants submit that these antibodies are conventional antibodies, generated in a conventional manner and illustrative of the instant invention. Accordingly, applicants respectfully submit that if these two monoclonal antibodies are adequately described, as concluded by the Examiner, then other monoclonal

antibodies are also adequately described. For at least the foregoing reasons, applicants submit they have satisfied the requirements of 35 U.S.C. § 112, first paragraph, and kindly request the withdrawal thereof.

In the Non-Final Office Action mailed April 9, 2007, the Examiner rejected Claims 17-24 under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while being enabled for methods of treating a human or animal suffering from the effects of infection with *Y. pestis,* comprising administering to the animal or human, a therapeutically effective amount of a medicament comprising monoclonal antibodies, Mab F1-040A-G1 and Mab 7.3, does not reasonably provide enablement for the methods as claimed. Applicants respectfully traverse.

Applicants respectfully submit that the antigens which give rise to these particular antigens, the F1 and V antigens, are known in the art to be highly immunogenic and therefore produce a wide range of antibodies. Indeed, many of these are known to be protective when used prophylactically (see for example abstract M125 from the SGM/SfAM Joint Main Symposium "Fighting Infection in the 21st Century" 10-11 April 2000, submitted herewith). Additionally, discussion on this matter can also be found in the instant application on page 3, lines 25-31, and the references mentioned therein. As a result, applicants submit that the state of the art around the antibodies themselves is well developed, and multiple protective antibodies have been found.

Applicants respectfully submit that the claimed method relates to the finding that antibodies of this type can be used in **therapy**, to treat subjects who have **already** suffered exposure to *Y. Pestis*. The results in this case indicate that antibody therapy is effective in prolonging survival. This is unexpected and effectively expands the range of the therapy to a different patient group. Typically, the patients in the state of the art are generally healthy individuals. In the present method, the patients are already challenged or ill, and may be suffering from symptoms of the disease. Given that these individuals' immune systems have been exposed to a virulent strain of the infecting organism and the immune system has already begun to respond, it is not obvious what the effects of administration of a prophylactic vaccine type substance would be. Applicants submit one of ordinary skill in the art would not expect that there would be therapeutic benefits, as is demonstrated in the instant application. Accordingly,

applicants submit they are the first to develop and demonstrate the beneficial effects of the claimed invention and are therefore entitled to broad protection.

Applicants submit that this effect would also apply to other similar antibodies. Such antibodies are readily available as discussed above. Applicants respectfully submit that any experimentation necessary to ensure that a particular antibody would be effective in therapy is not undue in the context of the particular art and in view of the significant contribution made to the art by the present method.

For at least the foregoing reasons, applicants submit they have satisfied the requirements of 35 U.S.C. § 112, first paragraph, and kindly request the withdrawal thereof.

In the Non-Final Office Action mailed April 9, 2007, the Examiner rejected Claims 17-24 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse.

Applicants submit that none of the antibodies recited in the instant application were the subject of a deposit. Applicants submit that such a deposit is unnecessary in view of the above comments in the preceding rejection. Applicants submit it is apparent that the precise nature of the antibody used is not critical, and that a skilled person would be able to generate their own therapeutic antibodies to the specific antigens, as explain above.

For at least the foregoing reasons, applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Claim rejections under 35 U.S.C. §112, second paragraph

In the Non-Final Office Action mailed April 9, 2007, the Examiner rejected Claims 20 and 23-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Applicants submit no amendment is necessary to Claims 20 and 23 because applicants have amended the specification to incorporate U.S. Patent 5,985,285 that discloses the V-antigen sequence. Applicants submit that the amendments to the specification provide a baseline sequence of the V- antigen, to which the Examiner is referring.

Claims 24 and 32 are amended herein to correct typographical errors in the claims. Claims 24 and 32 now recite "parenteral" administration. Support for the above amendments can be found on page 6, line 28 – page 7, line 2 of the published PCT application.

Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

CONCLUSION

In light of the amendments and the above remarks, applicants are of the opinion that the Non-Final Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404)-815-6473 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies that may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Respectfully submitted,

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